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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
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09/760,085

01/12/2001

Jaap Goudsmit

9250-28CT

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08/09/2006

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RALEIGH, NC 27627

EXAMINER

TUNG, JOYCE

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|  |                                      |  |  |
|--|--------------------------------------|--|--|
| <p align="center"><b>Advisory Action</b><br/><b>Before the Filing of an Appeal Brief</b></p> | <b>Application No.</b><br>09/760,085 | <b>Applicant(s)</b><br>GOUDSMIT ET AL. |  |
|  | <b>Examiner</b><br>Joyce Tung        | <b>Art Unit</b><br>1637                |  |

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 17 July 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☒ Applicant's reply has overcome the following rejection(s): the rejection of claims 45-58 under 35 U.S.C., first paragraph.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: \_\_\_\_\_.  
 Claim(s) objected to: \_\_\_\_\_.  
 Claim(s) rejected: 16-21, 28-31, 39-41 and 43.  
 Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
Please see the Attached.  
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_  
 13. ☐ Other: \_\_\_\_\_.

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1. The applicant's response filed 7/17/2006 to the Office action has been entered. Claims 16-21, 28-31, 39-41 and 43 are pending.
2. The rejection of claims 45-58 under 35 U.S.C. 112, first paragraph is withdrawn because of the cancellation of the claims.
3. Claims 16-21, 28-31, 39-41 and 43 remain rejected under 35 U.S.C. 102(b) as being anticipated by Bastian et al. (WO 95/21849 (US 6,180,778 used herein as translation)).

Bastian et al. disclose a method of separating nucleic acid mixture into their double stranded and single stranded fraction. All nucleic acids are simultaneously adsorbed in a mineral substrate, then separated by fractional elution into double stranded and single stranded nucleic acids, or double stranded and single stranded nucleic acid of a sample are selectively adsorbed in a mineral substrate (See the Abstract). The double stranded nucleic acid predominantly binds to the first mineral support and after optionally performed washing steps, can be eluted under conditions for low ionic strength or with water (See column 3, lines 23-28). The non-adsorbed single-stranded nucleic acid collected are subsequently adjusted and can be adsorbed to a second mineral support and become eluted under conditions of low ionic strength or with water (column 3, lines 30-36). The treatment condition contains a chaotropic substance (See column 4, lines 12-16). The mineral support consists of porous or non-porous metal oxides, silica gel or glass (See column 6, lines 6-21). The particle size is 0.1 um to 1000um (See column 6, lines 6-12). For binding double stranded nucleic acid to mineral supports, the solution contains quaternary ammonium thiocyanate with concentration 1 to 8 M and EDTA with the concentration from 5 mM to 200mM (See column 6, lines 49-58). Centrifuge is involved for pelletizing the silica material (See column 8, lines 53-54). Magnesium chloride, in concentration of from 0.1 to 10M may also

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be in combination for lysing or binding the sources containing nucleic acids (See column 5, lines 61-67 and column 15, claims 11-14). The complexes comprise alkaline earth metal ions bound to EDTA (See column 16, claim 22). Since the language “consisting essentially of” is considered to be open language, and in the specification, there is no clearly indication that alcohol is not allowed in the purification procedure, the teachings of Bastian et al. anticipate the limitations of claims 16-21, 28-31, 39-41 and 43.

For the purpose of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are “consisting essentially of” will be constructed as equivalent to “comprising”. See e.g. PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 (“PPG could have defined the scope of the phrase consisting essentially of for purpose of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention.”).

If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of “consisting essentially of,” applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicants invention. In re De lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA1964). See also ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989).

Accordingly, for the purposes of prior art, the claim limitation “consisting essentially of” is read as comprising and does not exclude the use of alcohol.

The response filed 7/17/06 discussed the teachings of Bastian et al. in which the variations of the concentration of materials containing alcohol groups in a binding solution

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influenced the binding characteristics of the single stranded nucleic acid or double stranded nucleic acid for nucleic acid purification. This is not found convincing because the instant specification is silent in this regard; it is submitted that Bastian et al. cannot be relied on. Thus, for the purposes of prior art, the claim limitation “consisting essentially of” is read as comprising and does not exclude the use of alcohol. Thus, the rejection is maintained.

### **Summary**

4. No claims are allowed.
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

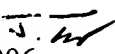
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Joyce Tung   
August 4, 2006

  
KENNETH R. HORLICK, PH.D.  
PRIMARY EXAMINER  
8/7/06